disorders. *See, e.g.*, page 29, lines 20-27; page 30, lines 19-22; and page 31, lines 6-11. Contrary to the Examiner's assertion, the disclosure that expression of the claimed polypeptide is significantly altered (enhanced or decreased) in several diseases does not negate the specificity of the diagnosis of any one of those diseases. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id. See also In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). Additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. *See, e.g., Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.") Thus, the Examiner's characterization of the specification's teaching of altered expression in asthma as "tantamount to no assertion at all" is improper; the specification clearly asserts several utilities for the claimed polypeptides, and Applicants have shown that the invention meets at least one of the asserted objectives. Accordingly, Applicants respectfully assert that the rejection of the claims under 35 U.S.C. § 101 has been obviated, and should be reconsidered and withdrawn.

Further, the Federal Circuit has held that the utility requirement of 35 U.S.C. § 101 and the "how to use" requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches more than one specific, substantial, and credible utility of the claimed invention, thereby enabling the skilled artisan to use the claimed antibodies. Since the specification teaches more than one specific and immediate utility for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

II. Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written Description

The Examiner has rejected claims 166-172 under 35 U.S.C. § 112, first paragraph, alleging that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More particularly, the Examiner contends that the application does not disclose fragments of at least 30 and 50 amino acid residues of SEQ ID NO:4, but rather fragments of variants.

In response, Applicants respectfully disagree. The paragraph relied upon by the Examiner recites:

> The polypeptides of the present invention include the polypeptides encoded by the deposited cDNAs; a polypeptide comprising amino acids ... about 1 to about 311 in SEQ ID NO:4 ...; a polypeptide comprising amino acids ... about 2 to about 311 in SEQ ID NO:4 ...; as well as polypeptides which are at least 95% identical, still more preferably at least 96%, 97%, 98% or 99% identical to the polypeptides described above and also include portions of such polypeptides with at least 30 amino acids and more preferably at least 50 amino acids.

The Examiner's reading of this paragraph rests on the assumption that "such polypeptides" references the percent identities, not the polypeptides described above, such as 1-311 and 2-311 of SEQ ID NO:4. Applicants respectfully assert that the Examiner's reading of this paragraph is incorrect; since the percent identity clause references "the polypeptides described above," it is only reasonable for the following clause to also reference "the polypeptides described above," when stating "such polypeptides." Indeed, the later references in the specification to such fragments (in the context of antigenic fragments) do not include percent identical language, adding further support for this reading of "such polypeptides."

Accordingly, Applicants respectfully request that the instant rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Enablement

The Examiner has rejected claims 166-172 under 35 U.S.C. § 112, first paragraph, alleging that the specification "fails to teach how to use said broadly claimed fragments of SEQ ID NO:4."

Applicants respectfully disagree. In particular, Applicants note that as the Examiner has noted, the specification discloses that antigenic peptides of the invention include those embraced by the present claims. With respect to the Examiner's reference to three specific antigenic regions identified in the specification, Applicants point out that the specification states that these are "non-limiting examples." Indeed, the specification specifically notes that, "Methods for determining other such epitope-bearing portions of the galectin 8, 9, 10, and 10SV proteins are described in detail below."

With respect to the use of the polypeptides of claims 166-172, the specification teaches that:

> ...it is well known in that art that relatively short synthetic peptides that mimic part of a protein sequence are routinely capable of eliciting an antiserum that reacts with the partially mimicked protein. See, for instance, Sutcliffe, J. G., Shinnick, T. M., Green, N. and Learner, R.A. (1983) Antibodies that react with predetermined sites on proteins. *Science 219:*660-666. Peptides capable of eliciting protein-reactive sera are frequently represented in the primary sequence of a protein, can be characterized by a set of simple chemical rules, and are confined neither to immunodominant regions of intact proteins (*i.e.*, immunogenic epitopes) nor to the amino or carboxyl terminals.
>
> Antigenic epitope-bearing peptides and polypeptides of the invention are therefore useful to raise antibodies, including monoclonal antibodies, that bind specifically to a polypeptide of the invention. See, for instance, Wilson *et al., Cell 37*:767-778 (1984) at 777.

Accordingly, it was known in the art as of the filing date that for raising antibodies, the preservation of the native three-dimensional structure of the protein was not required, antibodies to portions of the primary sequence were frequently used for epitope mapping, analysis of protein structure, and the like. Thus, it is clear that one skilled in the art would have been immediately able to use the polypeptides of claims 166-172 without undue experimentation. Applicants respectfully request that the instant rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns

and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

Should any additional fees be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: March 21, 2006

Respectfully submitted,

By _____

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